HFT-35

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

WARNING LETTER

February 20, 1997 WL-11-7

Michael J. Kelly, Ph.D.
President
Irvine Scientific, Inc.
2511 Daimler Street
Santa Ana, CA 92705-5588

Dear Dr. Kelly:

During an inspection of your manufacturing facility conducted between January 17 to February 4, 1997, our investigator determined that your firm manufactures in-vitro diagnostic products, medias, and cell cultures. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

Our investigation revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, or storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and control written manufacturing specifications and processing procedures to assure that the design basis for the device and packaging is correctly translated into approved specifications [21 CFR 820.100]. For example, our investigation determined that your firm has no documented evidence which provides a high degree of assurance that the manufacturing specifications and processing controls used in the manufacturing processes for your devices will consistently produce a product meeting its pre-determined specifications and quality attributes, traditionally termed validation. Specifically, our investigation determined that your company has not validated the lyophilization process used in the production of liquid medias.

2. Failure to conduct investigations and prepare written records of investigations, including conclusions and follow-up measures of devices which fail to meet their performance specifications [21 CFR 820.162]. For example, our investigation disclosed that particulates were found in fifty seven (57) vials of your Modified Sperm Wash and no investigation was performed to ascertain the cause and the effects of these particulates.

3. Failure to ensure that all necessary environmental conditions are controlled and monitored to prevent contamination or damage to devices and provide proper conditions for each of the operations [21 CFR 820.46]. For example, our investigation disclosed that your firm has not conducted any evaluations to determine the bioburden of the apparel used by your production and quality assurance personnel assigned to your environmentally controlled production areas. Our investigation also disclosed that fungi was discovered in these environmentally controlled areas and on employees apparel. Our records also show that your firm has recalled a lot of synthetic serum substitute for fungus contamination. We also understand that your firm has not completed its evaluation(s) to determine the effects of your sanitizing procedures and solutions used to clean your environmentally controlled production areas.

This letter is not intended to be an all-inclusive list of deficiencies at your facility and/or with your devices. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that your firm has submitted written response to this office concerning our investigator's observations noted on the form FDA 483. It appears that the response is adequate. A follow-up inspection will be required, however, to assure that corrections are adequate. Your written response indicates that all the necessary corrections will be completed by April 30, 1997, should these corrections take longer please advise our office of the anticipated completion date in order we can schedule our follow-up inspection.

Until it has been determined that corrections are adequate, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending submissions for premarket clearance for devices to which the GMP violations are reasonably related will be cleared. Also, no requests for Certificates For Products For Export will be approved.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. Such actions includes, but is not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the anticipated date that your facility

will be ready for reinspection.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard
Irvine, California 92715-2445

Sincerely,

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
714 "P" Street, Room 440
Sacramento, California 95814